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10/561,366	05/15/2006	Stephen Paul Collingwood	PR/4-33239A	9747
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CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/561,366

## Applicant(s)

COLLINGWOOD ET AL.

## Examiner

Celia Chang

## Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 11, 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election *without* traverse of group II with example 13 of table 2 as the elected species in the reply filed on May 26, 2009 is acknowledged.

Claims 12-15 have been canceled.

Claims 1-3, 8-9, 11, 16-18 reading on pyrrolidinyl compounds are prosecuted. Claims 4-7, 10, 19-22 and the remaining subject matter of claims 1-3, 8-10, 16-18 are withdrawn from consideration per 37 CFR 1.142(b).

An error was noticed in listing the claim numbers in the restriction requirement. Claim 10 is considered a multiple component material which should be grouped together with group III. Claim 11 is a composition of compounds of claims 1-3, 8-9, therefore should be grouped with groups II election.

2. Claims 1-3, 11, 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusing as for the definitions of L and M being CH<sub>2</sub>, CH<sub>2</sub>CH<sub>2</sub> or bond. It is unclear whether the Markush elements are CH<sub>2</sub>, CH<sub>2</sub>CH<sub>2</sub> and bond or when L is CH<sub>2</sub>, M is CH<sub>2</sub>CH<sub>2</sub> etc. It is recommended that the exact structure be delineated for pyrrolidinyl ring.

Broadly, the claims are interpreted to be L or M is bond, CH<sub>2</sub> or CH<sub>2</sub>CH<sub>2</sub> and in combination to form a pyrrolidinyl ring and J is bond or C1-C2 alkylene for the following rejections.

3. Claims 1-3, 11, 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds using formula VI to make the resulted pyrrolidinyl compounds of tables 2 and 4, does not reasonably provide enablement for the scope as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is noted that Boder US 7,399,861 disclosed compounds wherein R5 is substituted by COOR which was encompassed by the claims (see col. 48, compounds 4 and 5). However, none of the compounds of tables 2 or 4 was substituted by  $-(CO)-OR6$ . Therefore, the issue of whether applicants are the first in possession of such broad scope must be raised.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

As correlated to section 3, claims 1-3, 11, 16-18 reading on J=bond compounds are rejected over US 7,399,861 directed to the same invention on col. 48. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 11, 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Prat et al. WO 03/087094 supplemented with CA 139:337885.

See structural delineation from CA139 of anticipatory compounds disclosed by the WO patent.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8-9, 11, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO03/087094 in view of Ogino et al. US 6,846,835.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

WO03/087094 and Ogino et al. '835 are analogous art on the muscarinic receptor active compounds. The anticipatory compounds were delineated by CA139 as recited supra.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the prior art compounds and the instant claims when J is not bond such as those of claims 8-9, is that a methylene moiety is inserted between the pyrrolidinyl moiety and the carboxylic moiety i.e. J is CH<sub>2</sub>. The insertion of a methylene chain in a known compound is ordinarily considered prima facie obvious for structural closeness, i.e. see In re Ruddy 121 USPQ 427; Ex parte Nathan 121 USPQ 349. In the instant case, such insertion has been taught to be alternative choices for such compounds, see Ogino et al. '835 col. 7, formula A2, k being 0, 1 or 2.

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art in possession of the above references with multiple exemplification delineated by CA139 would be tantamount to in possession of the one methylene inserted compounds because not only one methylene insertion is structurally very close to the prior art compound but also it has been clearly conventional to one skilled in the art that such modification is indeed an optional choice without affecting biological activity. One skilled in the art would be motivated to modify the well delineated compounds of CA139 with one methylene insertion with the suggested expectation that the modified compounds would be active. The teaching, suggestion and motivation have been conventionally found in the prior art and the modification of a known compound with attributes conventional to such compounds is prima facie obvious.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Mar. 1, 2010*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*